REMARKS

Some of the claims 1-36 were previously cancelled. The rest of the claims 1-36 are hereby canceled, thereby addressing the Examiner's objection to the drawings.

The Examiner has rejected previous claim 32 under §112. The Examiner has rejected some claims as being anticipated by Chee '937 and by Wang '024 and the rest of the claims as obvious over the combined Chee or Wang teachings in view of the Parker '830 patent.

The claims have been rewritten in part to overcome the Examiner § 112 rejection and in part to more clearly distinguish over the references.

Applicant notes that the teachings of Chee '937, represented in Fig. 6, are to a change in the relative thickness of two layered polymers 142 and 144 over an intermediate section of the catheter. This change in ratio is achieved by changing the thickness of each of the two layers in this intermediate or transition zone.

By contrast, Applicant teaches and now clearly and unambiguously claims a transition segment in which there is a continuously varying mixture of two polymer materials having different weights of radiopaque filler. This mixture, rather than a layering, is one of the distinguishing features of the combination that constitutes Applicant's claimed design.

Layering of two polymers so that they are sealed to one another creates a delaminating issue which effectively limits the burst strength of the tube. The mixing of the two materials however overcomes that delaminating problem and provides a more secure and higher burst strength.

Claim 37, the sole independent claim in this case, has been written in part to meet the Examiner's rejections under § 112 and, more importantly, to meet the Examiner's rejections based on the cited art.

This invention is addressed to the problem of combining two different hardness polymers and two different levels of radiopaque filler to provide a first set of hardness and radio-opacity parameters at the proximal end and a second set of hardness and radio-opacity parameters at the distal end and to do so while meeting the requirement of a smooth transition between proximal and distal segments that avoids any tendency to kink and that also provides a high burst strength at the proximal end. This combination takes into account that radiopaque filler tends to increase hardness.

Applicant solves this problem by having a transition segment in which a two polymer mix continuously and smoothly varies from high to low in a distal direction and a radiopaque filler weight continuously and smoothly varies from high to low in a proximal direction.

Radiopaque filler tends to increase the stiffness of the polymer material. Accordingly, to achieve the objective of minimizing tissue trauma at the distal end, the distal segment polymer must be very flexible and soft. This requirement increases the importance of having an appropriate transition to the much higher durometer and stiffer polymer needed at the proximal end.

Accordingly, varying polymer durometer has to be coupled with varying radiopaque filler weight. This combination provides the desired soft distal end and hard proximal end. Meeting these objectives is achieved by having a particular transition segment between the proximal high durometer segment and the distal low durometer segment. The transition segment varies in stiffness of durometer in a continuous even rate throughout the transition segment. This continuous varying hardness is achieved by the combination of (a) a continuously varying mixture of harder proximal plastic with softer distal plastic and (b) a continuously varying weight of radiopaque filler from a lower weight at the proximal end of the transition segment to a higher weight at the distal end of the transition segment.

The provision of two continuously varying constituents through the transition segment assures there is no sudden jump or discontinuity in the hardness parameter. This therefore avoids the stress points caused by discontinuities and avoids compromising characteristics such as burst strength and resistance to kinking.

The Cited Art

The art cited by the Examiner does not teach or suggest or make obvious the combination that is set forth in the claims.

The Chee '937 Patent does not consider or address the handling of the situation where there are two different polymers each with radiopaque filler, much less where the weight of that radiopaque filler differs in the two polymers.

Similarly, the Wang '024 Patent does not address the issue of how the two polymer materials are handled or combined where each has a different weight of radiopaque filler.

The Parker '830 Patent does show a catheter having radiopaque material. But Parker provides teachings which would lead one away from Applicant's design.

In particular, Parker calls for bonding surfaces and for braid material 26 in the proximal portion.

If one took the teachings of Parker and adapted them to the teachings of either Wang or Chee, one would come up with an essentially meaningless design. The design would be meaningless because the teachings of these patents contradict each other. Applicant suggests that even in hindsight, one would not be able to select features from these three patents in any combination that would result in Applicant's invention.

At the best, Parker shows the use of radiopaque particles 35 in the polymer tubing. But there is nothing in Parker that can be adapted to either the Wang or Chee design for handling the situation where there is a need for both (a) different hardness at the proximal and distal ends coupled with (b) different radio-opacity at the proximal and distal ends.

Accordingly, Applicant believes that the claims in this case are allowable and such is respectfully requested.

The Commissioner For Patents is hereby authorized to charge any additional fees to Deposit Account No. 03-3415.

Respectfully submitted,

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